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| 09/937,357 | 09/24/2001 | Nicholas F. D'Antonio | DA7119US (#90036) | 7922 |
| 28672 | 7590 | 02/05/2004 | EXAMINER | |
| D. PETER HOCHBERG CO. L.P.A. 1940 EAST 6TH STREET CLEVELAND, OH 44114 | | | LAM, ANN Y | |
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1641

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,357

Applicant(s)

D'ANTONIO ET AL.

Examiner

Ann Y. Lam

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-- The MAILING DATE of this communication appears on the cover sheet with the corresponding address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2001 and 01 April 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-63 is/are pending in the application.
- 4a) Of the above claim(s) 36-47 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-35 and 48-63 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This supplemental Office action is necessary to correct the errors in the previous Office action dated March 24, 2003, wherein the action did not specifically address all the claims that were added in the two preliminary amendments. Examiner apologizes for any inconvenience this may have caused.

Also, Applicant's paper filed October 28, 2003 is considered an informal paper. Examiner's unofficial office action (i.e., the unsigned action dated May 23, 2003) was never signed or mailed. Examiner apologizes for any inconvenience. The present office action basically contains the same material as the unofficial May 23, 2003 action, and will set a new period for response.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 1-35, and 48-63, drawn to an injection device classified in class 604, subclass 191.
- II. Claims 36-47, drawn to a station for re-energizing an injection system, classified in class 604, subclass 235.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2)

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that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination of the injection device and loading station do not require the particular claimed elements in the subcombination as claimed. The subcombination has separate utility such as loading an injection device different from the one claimed by Applicant in the combination.

During a telephone conversation with Peter Hochberg on March 20, 2003 a provisional election was made without traverse to prosecute the invention of Invention I, claims 1-35. Affirmation of this election must be made by applicant in replying to this Office action. Claims 36-47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-18, 20-35, 48-54 and 59-63 are rejected under 35 U.S.C. 102(b) as being anticipated by D'Antonio et al., 6,056,716.

As to claims 1, 2, 12, 13, 21, 48, 59, 60, 62, D'Antonio et al. discloses a housing (913), a container-holding member (921) for holding injectate containers (800); and a

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latching and release apparatus (see column 23, lines 12-17) for latching holding member to housing and for releasing said holding member and the container held by said holding member from said housing without any physical contact by the user; an actuable injectate release device (703) for applying pressure on the respective injectate containers to transmit injectate from said containers for the injection process, said injectate release device comprises energy storage apparatus (227) for storing energy to be applied to the respective injectate containers; and a manually operable trigger device (701); wherein said trigger device actuates said storage apparatus to cause said energy storage apparatus to apply energy to the respective containers and transmit the injectate from the containers.

As to claims 3, 22, 25, guard walls (805) are provided around said openings.

As to claim 4, splash guard walls (919) are provided around container-holding member.

As to claim 5, the openings are press fit with injectate containers, see column 22, lines 47-66, and see Figure 7A.

As to claim 6, said housing has a front portion, said holding member comprises a front plate and said latching and release apparatus includes a groove (919) in one of said front plate and said housing and a releasable latching member in the other of said front plate and said housing for releasably entering said groove to latch said front plate to said housing, see column 22, lines 57-67.

As to claim 7, also disclosed is an actuable injectate release device (703) for applying pressure on the respective injectate containers to transmit injectate from said

containers for the injection process, and a manually operable trigger device (701) for actuating said injectate release device.

As to claims 8 and 9, said injectate release device comprises a spring (227) and latch for holding spring in set condition, see column 16, lines 40-49.

As to claim 10, said locking an release apparatus comprises at least one locking member for cooperating with said container-holding member to lock said holding member to said housing, device for releasing said locking member to enable said holding member to be properly positioned on said housing and for activating said locking member to lock said properly positioned holding member to said housing, and an ejection device for ejecting said holding member and the respective containers held by said holding member from said housing, see column 23, lines 1-3, and lines 12-17.

As to claim 11, said holding member (921) is a plate with a peripheral edge having a groove, see Figure 7A, and said locking member enters said groove to lock said plate to said housing, said locking member being removable from said groove to release said plate, see column 23, lines 1-3, and lines 12-17.

As to claim 14, one of said cartridges is considered inactive cartridges having pseudo-channels.

As to claims 20, 49, D'Antonio discloses a housing (913) for housing at least two injectate cartridges (800) for an injectate to be injected from the system into a body, the cartridges having perforators (882) for piercing the skin of a body and through which injectate flows during an injection process, see column 27, lines 65-67; a member (921) for holding the respective injectate cartridges in position during the injection process for

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proper injection into the body; and latching and release apparatus for releasably latching said cartridges held by said member from said housing without any physical contact by the user, for non-contaminating disposal after the injection process, see column 23, lines 1-3, and lines 12-17.

As to claims 23, 24, 26, 27, 28, 50 and 61, D'Antonio discloses a housing (913) for housing at least two injectate cartridges (800) for an injectate to be injected from the system into a body, the cartridges having perforators (882) for piercing the skin of a body and through which injectate flows during an injection process, see column 27, lines 65-67; a member (921) for holding the respective injectate cartridges in position during the injection process for proper injection into the body; a ram apparatus (849) having separate rams (848), each movable with respect to one of said cartridges to move the respective plungers for forcing injectate from said cartridges through the dispensing channels and the individual exit nozzle; a carriage for moving said ram apparatus, see column 27, lines; a spring apparatus with movable rods (227 or see column 26, lines 61-64) for moving said carriage; a carriage resetting apparatus (436) for moving said carriage to the set position and for recocking said spring apparatus, see column 10, line 46 – column 11, line 20, and a releasable latching device for latching said spring apparatus is disclosed, see column 11, lines 14-20.

As to claims 29, 32 a cam and cam follower as claimed is disclosed, see column 10, lines 46-59.

As to claim 30, a solenoid as claimed is disclosed at (48).

As to claims 31, 33, a drive apparatus moved by a motor driven device (221) is disclosed, see column 9, line 63 – column 10, line 17.

As to claim 51, D'Antonio discloses a housing (913) for housing at least two injectate cartridges (800) for an injectate to be injected from the system into a body; a member (921) for holding injectate containers; and a latching and release apparatus (see column 23, lines 12-17) held by said member from said housing without any physical contact by the user, for non-contaminating disposal after the injection process.

As to claims 15-18, 52 and 63, D'Antonio discloses a housing (913) for housing at least one cartridge (800) for an injectate to be injected from the system into a body; disposable injectate-cartridges (800) including: an outer wall having an inner wall surface defining an inner chamber, see Figure 7A and Figure 8A; and a plunger (802) engaging said inner wall surface and being movable in said chamber; said plunger defining an injectate-holding portion of said chamber, said injectate-holding portion of a least one cartridge comprising a rupturable seal, see column 27, line 58 – column 28, line 5, dividing said holding portion into two compartments, one of said compartments holding a lyophilized part of an injectate, see column 20, lines 63-67, and the other of said compartments holding a predetermined amount of fluid for mixing the components of the injectate, see column 4, lines 49-50, column 16, lines 59-64; and said chamber having an injectate dispensing end having an exit nozzle, see Figure 8A, said plunger being drivable into said injectate-holding portion to dispense the injectate through said nozzle during the injection process; latching and release apparatus for releasably latching of said cartridges held by said member to said housing during the injection

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process, and for releasing said cartridge held by said member from said housing without any physical contact by the user, for non-contaminating disposal after the injection process, see column 23, lines 1-3, and lines 12-17; and a device (702) for rupturing the seal of said cartridges, see column 28, lines 1-5.

As to claim 34, a loading station to operate said carriage resetting apparatus is disclosed, see column 10, lines 10-17.

As to claim 35, a sensing apparatus as claimed is disclosed in column 24, lines 24-27.

As to claim 53, D'Antonio discloses a housing (913) for housing at least one injectate container, a container-holding member (921) for holding injectate containers (800); and a latching and release apparatus (see column 23, lines 12-17) for releasably latching said holding member to housing and for releasing said holding member and the container held by said holding member from said housing alternatively either without any physical contact by the user, or with physical contact by the user.

As to claim 54, said container-holding member (921) is configured to hold at least two injectate containers, see Figure 7A, and said system has exit nozzles arranged to inject injectate while preventing the overlap of the injectate from each exit nozzle during the injection process, see Figure 7A.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 19, 55-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over D'Antonio et al., 6,056,716.

D'Antonio et al. discloses the invention substantially as claimed, see above, except for there being six injectate containers. Furthermore, as to claim 56, the exit nozzles are arranged in a rectangle as claimed. D'Antonio discloses five cartridges and providing a device with six cartridges would not depart from the scope of the invention, see column 30, lines 43-46. The optimum number of cartridges can be determined by routine experimentation and thus would have been obvious to one of ordinary skill in the art.

As to claims 57 and 58, it would have been obvious matter of design choice to modify the D'Antonio reference by having the exit nozzles be arranged in a circle as claimed since applicant has not disclosed that having the nozzles be arranged in a circle solves any stated problem or is for any particular purpose and it appears that a circular arrangement would perform equally well as a rectangular arrangement.


Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on M-TH 8-6:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703)305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)308-4426 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.

A.L. 
January 27, 2004


CHRISTOPHER L. CHIN
PRIMARY EXAMINER
GROUP ~~1800~~/641